

CLAIMS

- 5 1. A method for inactivating a transmissible spongiform encephalopathy (TSE) agent comprising exposing the TSE agent to a thermostable proteolytic enzyme.
- 10 2. The method of claim 1, comprising exposing the TSE agent to the thermostable protease at a temperature that is equal to or greater than 40°C.
3. The method of claim 2, wherein the temperature is between 50°C and 120°C.
4. The method of claim 3, wherein the temperature is between 55°C and 85°C.
- 15 5. The method of claim 1, comprising exposing the TSE agent to the thermostable proteolytic enzyme at alkaline pH.
6. The method of claim 5, wherein the pH is from 8 to 13.
- 20 7. The method of claim 5, wherein the pH is from 10 to 12.
8. The method of claim 1 wherein the TSE agent is a prion.
- 25 9. The method of claim 8, wherein the TSE agent is selected from the group consisting of Creutzfeld-Jacob disease; variant Creutzfeld-Jacob disease; Kuru; fatal familial insomnia; Gerstmann-Straussler-Scheinker syndrome; bovine spongiform encephalopathy; scrapie; feline spongiform encephalopathy; chronic wasting disease; and transmissible mink encephalopathy.
- 30 10. The method of claim 1, wherein the thermostable proteolytic enzyme is obtained from a thermophilic organism selected from the group consisting of archaea; hyperthermophilic bacteria and thermophilic bacteria.
- 35 11. The method of claim 10 wherein the thermophilic organism is selected from the group consisting of *Thermotoga maritima*; *Thermotoga neopolitana*;

Thermotoga thermarum; *Fervidobacterium islandicum*; *Fervidobacterium nodosum*; *Fervidobacterium pennivorans*; *Thermosiphon africanus*; *Aeropyrum pernix*; *Thermus flavus*; *pyrococcus* spp.; *Sulfolobus solfataricus*; *Desulfurococcus*; *Bacillus thermoproteolyticus*; *Bacillus stearo-thermophilus*; *Bacillus* sp. 11231; *Bacillus* sp. 11276; *Bacillus* sp. 11652; *Bacillus* sp. 12031; *Thermus aquaticus*; *Thermus caldophilus*; *Thermus* sp. 16132; *Thermus* sp. 15673; and *Thermus* sp. Rt41A.

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12. A method of sterilising apparatus comprising exposing said apparatus to a solution comprising a thermostable proteolytic enzyme.
13. The method of claim 12, wherein the solution is maintained at a temperature below 100°C.
14. The method of claim 12, wherein the solution is maintained at a temperature of between 45°C and 85°C.
15. The method of claim 12, wherein the solution has an alkaline pH.
16. The method of claim 15, wherein the solution has a pH of between 8 and 13.
17. The method of claim 12, wherein the thermostable proteolytic enzyme is obtained from a thermophilic organism.
18. The method of claim 17 wherein the thermophilic organism is selected from the group consisting of archaea; hyperthermophilic bacteria and thermophilic bacteria.
19. The method of claim 12, wherein the solution is applied to the apparatus as a spray.
20. The method of claim 12, wherein the apparatus is immersed in the solution.
21. A method of sterilising apparatus, comprising exposing said apparatus to a first solution comprising a first thermostable proteolytic enzyme; and exposing the apparatus to at least a second solution comprising a second thermostable

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proteolytic enzyme.

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22. The method of claim 21, wherein the first and second proteolytic enzymes are the same.
23. The method of claim 21, wherein the first proteolytic enzyme is different to the second proteolytic enzyme.
- 10 24. The method of claim 21, wherein the pH of the first solution is different to the pH of the second solution.
25. The method of claim 21, wherein the temperature of the first solution is different to the temperature of the second solution.
- 15 26. A composition for inactivating a TSE agent, comprising (1) a thermostable proteolytic enzyme and (2) a buffering agent having a pK_a of from 8 to 13.
- 20 27. The composition of claim 26, wherein the thermostable proteolytic enzyme is obtained from a thermophilic organism selected from the group consisting of archaea; hyperthermophilic bacteria and thermophilic bacteria.
28. Apparatus for inactivating a TSE agent comprising:-
- 25 a. a chamber for receiving contaminated material;
- b. means for controlling the temperature of the chamber; and
- c. a thermostable proteolytic enzyme active at alkaline pH, located within the chamber.
- 30 29. A method of examining a sample infected with or suspected to be infected by prion protein, comprising detecting dimers of prion protein in the sample.
- 35 30. An antibody, which is specific for prion dimer but does not bind to prion monomer.

31. The method of claim 1, wherein the thermostable proteolytic enzyme is a serine protease.
- 5 32. The method of claim 1, wherein the thermostable proteolytic enzyme is a subtilisin.
33. The method of claim 32, wherein the thermostable proteolytic enzyme is a subtilisin derived from *Bacillus* bacteria.
- 10 34. The method of claim 33 wherein the thermostable proteolytic enzyme is a subtilisin derived from *Bacillus amyloliquefaciens*, *Bacillus lentus*, *Bacillus licheniformis*, *Bacillus subtilis* or is subtilisin PB92.
- 15 35. The method of claim 1, wherein the thermostable proteolytic enzyme is selected from the group consisting of MC-A, MC-3 and MC-4.